

An international multicentre prospective audit of elective rectal cancer surgery

The 2017 European Society of Coloproctology (ESCP) collaborating group; Pinkney, Thomas

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An international multicentre prospective audit of elective rectal cancer surgery; operative approach versus outcome, including transanal total mesorectal excision (TaTME)

The 2017 European Society of Coloproctology (ESCP) collaborating group*

**Collaborating authors listed at end of manuscript*

Corresponding author:

Alaa El-Hussuna

European Society of Coloproctology (ESCP) Cohort Studies Committee

Department of Surgery

Aalborg University Hospital

Hobrovej 18-22

9100 Aalborg, Denmark

Email: alaanewemail@gmail.com

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Abstract

Introduction: Transanal total mesorectal excision (TaTME) has rapidly emerged as a novel approach for rectal cancer surgery. Safety profiles are still emerging and more comparative data is urgently needed. This study aimed to compare indications and short-term outcomes of TaTME, open, laparoscopic, and robotic TME internationally.

Methods: A pre-planned analysis of the European Society of Coloproctology (ESCP) 2017 audit was performed. Patients undergoing elective ~~TME~~ total mesorectal excision (TME) for malignancy between 1 January 2017 and 15 March 2017 by any operative approach were included. The primary outcome measure was anastomotic leak.

Results: Of 2579 included patients, ~~2204~~ patients undergoing TME, 83.4~~76.2~~% (~~1838~~1966/2204~~2579~~) underwent TME with restorative anastomosis of which 19.9% (~~365~~312/~~1838~~1966) had a minimally invasive ~~operation approach (laparoscopic or robotic)~~ which included a transanal component (TaTME). Overall, 9.0~~8.9~~% (~~163~~175/~~1838~~1951, 15 missing outcome data) of patients suffered an anastomotic leak. On univariate analysis both laparoscopic TaTME (OR 1.61, 1.02-2.48, p=0.04) and robotic TaTME (OR 3.05, 1.10-7.34, p=0.02) were associated with a higher risk of anastomotic leak than non-transanal laparoscopic TME. However this association was lost in the mixed-effects model controlling for patient and disease factors (OR 1.23, 0.77-1.97, p=0.39 and OR 2.11, 0.79-5.62, p=0.14 respectively), whilst low rectal anastomosis (OR 2.72, 1.55-4.77, p<0.001) and male gender (OR 2.29, 1.52-3.44, p<0.001) remained strongly associated. On univariable analysis, a transanal approach was significantly associated with increased anastomotic leak (12.8% versus 7.9%; OR 1.73, 1.20-2.46, p=0.003). However, this association was lost on multivariable analysis controlling for patient and disease factors (OR 1.33, 0.90-1.96, p=0.147), whilst any low rectal anastomosis

~~(OR 2.58, 1.47–4.54, p=0.001) and male gender (OR 2.28, 1.52–3.43, p<0.001) remained strongly associated.~~ The overall positive circumferential margin resection rate was 4.0%, which varied between operative approaches: laparoscopic 3.2%, transanal 3.8%, open 4.7%, robotic 1%.

Conclusion: This contemporaneous international snapshot shows that uptake of the TaTME approach is widespread and is associated with surgically and ~~oncologically–pathologically~~ acceptable results.

What this study adds

Approaches to rectal cancer resection vary across Europe. One in five patients is undergoing a TaTME approach, with results suggesting equivalent anastomotic leak and positive resection margin rates. Both robotic and TaTME approaches need further evidence to support their impact on major complications. Anastomotic leak rates in low rectal anastomoses remain high, regardless of operative approach.

Introduction

The best technique to achieve safe and effective total mesorectal excision (TME) for rectal cancer continues to pose a significant challenge for surgeons and patients. The ideal technique aims for an intact TME with clear circumferential and distal resection margins [1]. When reconstruction is planned, an ~~anastomotic technique is~~ anastomotic technique that minimises the risk of leak whilst promoting good function is needed. A significant challenge is posed by cancers in the lowest third of the rectum, particularly in a narrow pelvis. From an abdominal approach, the ability to pass a stapler safely below the tumour is vital to avoid an involved distal resection margin. Similarly, the need for multiple firings of a cross-stapler predisposes to anastomotic leak [2]. Finally, precise placement of circular stapling devices through cross-stapled rectal stumps can be challenging.

Transanal TME (TaTME) has been proposed as a method to improve surgery of mid and low rectal lesions [3, 42, 3]. It is typically performed as a hybrid procedure with a minimally invasive (laparoscopic or robotic) abdominal approach, with dissection and ultralow colorectal/coloanal anastomosis through the transanal port to improve visualisation and avoid cross stapling [54] or multiple firings [2, 55]. It has the potential to be ~~oncologically~~ safer for the distal resection margin by improving access and precision of dissection and stapler placement [2].

TaTME is still evolving (IDEAL Phase 2b) with ~~low-moderate~~ low-moderate stability ~~and reproducibility~~ of its components [6, 7]. A ~~steep and~~ steep prolonged learning curve [8] for transanal surgery has been described, with worse outcomes seen in as many as the first fifty cases performed [9]. Consistent with this, early series report anastomotic leak rates as high as 43% [10], with concerning rates of urethral and other solid organ injury. Concerns also exist about circumferential resection margin (CRM) involvement and suboptimal TME specimen grades in

its early adoption [9, 11]. There is not yet randomised evidence for the benefit of TaTME. A recent large and comprehensive registry study has identified baseline data and showed acceptable leak rates and safety profiles from the included centres [\[12\]](#). However, it did not have comparative groups to benchmark current practice, and so to supplement this, we planned a study from a wide range of centres to gather comparative data. The primary aim of this study was to describe the safety profile of TaTME compared to other surgical approaches to manage rectal cancer. The secondary aim was to additionally describe the current landscape in terms of uptake of TaTME and the alternate operative approaches for rectal cancer, including open, laparoscopic, and robotic TME.

Methods

Protocol and centres

This prospective, observational, multicentre study was conducted in line with a pre-specified protocol (<http://www.escp.eu.com/research/cohort-studies>). An external pilot of the protocol and data capture system was conducted in five international centres prior to launch, allowing refinement of the study tool and delivery. Any unit performing gastrointestinal surgery was eligible to register to enter patients into the study. No minimum case volume, or centre-specific limitations were applied. The study protocol was disseminated to registered members European Society of Coloproctology (ESCP), and through national surgical or colorectal societies, and represents a pre-planned analysis of the European Society of Coloproctology 2017 audit database.

Study approvals

All participating centres were responsible for compliance to local approval requirements for ethics approval or indemnity as required. In the UK, the National Research Ethics Service tool recommended that this project was not classified as research, and the protocol was registered as clinical audit in all participating centres.

Patient eligibility

Adult patients (>16 years) undergoing elective (planned) rectal resection with or without a primary anastomosis were extracted from the main audit database. Only operations performed for a malignant pathology within the rectum, up to the rectosigmoid junction were included. For the abdominal component, open, laparoscopic and robotic procedures were all eligible. Transanal and non-transanal approaches were acceptable. Rectal resections performed as part of a more extensive resection (e.g. panproctocolectomy ~~or subtotal colectomy~~) were excluded.

Data capture

Consecutive sampling was performed of eligible patients over an 8-week study period in each included centres. Local investigators commenced data collection on any date between the 1 January 2017 and 15 March 2017, with the last eligible patient being enrolled on 10 May 2017. This study adopted the UK National Research Collaborative model for data collection and follow-up. Small teams of up to five surgeons or surgical trainees worked together to collect prospective data on all eligible patients at each centre. Quality assurance was provided by at least one consultant or attending-level surgeon. Data was recorded contemporaneously and stored on a secure, user-encrypted online platform (REDCap) without using patient identifiable information. Centres were asked to validate that all eligible patients during the study period had been entered, and to attain >95% completeness of data field entry prior to final submission.

Outcome measure

The primary outcome measure was overall anastomotic leak, pre-defined as either i) gross anastomotic leakage proven radiologically or clinically, or ii) the presence of an intraperitoneal (abdominal or pelvic) fluid collection on post-operative imaging. The secondary outcome measures were the postoperative major complication rate; defined as Clavien-Dindo classification grade 3 to 5 (reoperation, reintervention, unplanned admission to critical care, organ support requirement or death), postoperative length of stay (in whole days); with day of surgery as day zero, the intraoperative serious adverse event (SAE) rate, and the circumferential resection margin involvement rate; defined as tumour tissue \leq 1mm from the resection margin.

Statistical analysis

This report has been prepared in accordance to guidelines set by the STROBE (strengthening the reporting of observational studies in epidemiology) statement for observational studies [12]. Patient, disease and operative characteristics were compared by type of surgical approach (open, laparoscopic - transanal (TaTME), laparoscopic - not transanal, robotic - transanal (TaTME), robotic - not transanal) and by the presence or absence of the primary outcome measure (anastomotic leak or intraperitoneal collection) using Student's t-test for normal, continuous data, Mann-Whitney U test for non-normal continuous data or Chi-squared test for categorical data. To test the association between overall anastomotic leak and approach (the main explanatory variable) two models were fitted: the first was a mixed-effects logistic regression model using the whole dataset, the second was a propensity score-matched group of patients who did and did not undergo TaTME in a 1:2 ratio. In the mixed-effects model, clinically plausible patient, disease and operation-specific factors were entered into the model for risk-adjustment, treated as fixed effects. These were defined *a priori* within the study protocol, and included irrespective of their significance on univariate analysis. Hospital was entered into the model as a random-effect, to adjust for hospital-level variation in outcome. Propensity score matching was used to estimate the effect of approach (transanal versus not transanal perineal approach) by accounting for confounding co-variables that might predict patient selection. Nearest neighbour matching was used with scores calculated from variables selected *a priori* for model adjustment (age, gender, anastomotic height, AJCC stage), and outputs were examined using jitter plots and Chi-squared testing to observe any significant differences between groups. A second propensity-score matched multivariable logistic regression model was then fitted to explore the association of operative approach and anastomotic leak. Effect estimates are presented as odds ratios (OR) with 95% confidence intervals (95% CI) and two-tailed p-values. An alpha level of 0.05 was used throughout. Model discrimination was tested by calculating a C-statistic (analogous to the area under the Receiver Operating Curve (AUC); 0.5: no discrimination; 0.6, adequate; 0.7, good; 0.8 excellent). Multiple

imputation was not required as the data completeness rate was very high for data points used for propensity score matching. Data analysis was undertaken using R Studio V3.1.1 (R Foundation, Boston, USA).

Results

Patient demographics

Figure 1 shows inclusion of patients within this study. A total of 2579 patients were included from 355 centres across 49 countries. The mean age of the cohort was 66 years (18-98 years), of which 27.7% (715/2579) had low, 26.0% (670/2579) had middle and 46.3% (1194/2579) had high rectal anastomoses. 62.7% were men (1617/2579) and 36.5% (942/2579) underwent neoadjuvant therapy, of which 72.1% (679/942) had long course chemoradiotherapy. A majority of tumours were either T2 (21.8%, 563/2579) or T3 (51.8%, 1337/2579), N0 (58.4%, 1505/2579) and M0 (87.7%, 2262/2579). The abdominoperineal resection rate was 15.4% (396/2579, Figure 2) and resection with end stoma formation was 8.4% (217/2579). Of those that had an anastomosis (76.2%, 1966/2579), 92.1% (1811/1966) had a stapled anastomosis.

Patient, disease and operative characteristics by operative approach

There was variation in the selection of patients for different approaches to rectal cancer surgery (Table 1). ~~Overall~~ Of patients undergoing restorative surgery, 15.9% (3412/25791966) of patients from 189 centres underwent surgery with a transanal perineal approach and minimally invasive abdominal approach (TaTME), ranging from one to 15 submitted cases per centre.

~~6.46% (469126/25791966)~~ of patients from 40 centres had robotic surgery (ranging from one to 18 submitted case per centre). In patients undergoing TaTME, which the anastomosis was was stapled in 73.74.9% (230/3124) and handsewn in 26.0% (81/3124).

The proportion of males ~~in undergoing~~ transanal and robotic approaches was slightly higher when compared to the other procedures (68.4%, 68.3%, 64.4% versus 61.8%, 60.6% respectively; p=0.06). Transanal or robotic approaches were significantly more likely to be selected in low risk ASA 1-2 patients and earlier stage disease. An anastomosis was formed in 75.5% of patients (311/412) who underwent transanal approach, which was stapled in 74.0% (230/311) and handsewn in 26.0% (81/311).

Anastomotic leak

~~The~~ Within the patients undergoing restorative anastomosis, the overall anastomotic leak rate was 9.0% (175/1945, with 15 missing outcome data (<1%)). In the unadjusted data, the anastomotic leak rate was higher in transanal-TaTME (12.9%, 404/311, one missing outcome data (<1%)) versus than non-transanal surgery-TME (8.9%, 135/1520; Figure 3).

The highest leak rate was seen in robotic surgery, and more major complications were seen in transanal and robotic surgery (Table 2). In the univariate analysis both laparoscopic TaTME (OR 1.61, 1.02-2.48, p=0.04) and robotic TaTME (OR 3.05, 1.10-7.34, p=0.02) were associated with a higher risk of anastomotic leak than non-transanal laparoscopic TME. Once adjusted for confounders (Table 3, Figure 4), transanal surgery was no longer significantly associated with leak (OR 1.23, 0.77-1.97, p=0.39 and OR 2.11, 0.79-5.62, p=0.14 respectively OR 1.33, 0.90-1.96, p=0.147), whilst low rectal anastomosis (OR 2.72, 1.55-4.77, p<0.001 OR 2.58, 1.47-4.54, p=0.001) and male gender (OR 2.29, 1.52-3.44, p<0.001 OR 2.28, 1.52-3.43, p<0.001) were strongly associated. The model demonstrated acceptable-fair discrimination (AUC: 0.70). Propensity score matching gave balanced groups (Table 4). In the propensity matched multivariable model (Table 5, Figure 5), transanal approach was not associated with overall anastomotic leak (OR 1.14, 0.70-1.81, p=0.595). However, male gender (OR 2.88, 1.64-5.38, p<0.001) and low rectal anastomosis (OR 3.92, 1.74-10.52, p=0.002) again remained strong predictors for anastomotic leak.

Circumferential resection margin

In the unadjusted data, restorative surgery had a lower CRM positivity rate (36/1733, with 232 missing outcome data (11.8%)) than non-restorative (58/549) operations (2.3% versus 10.6%).

Overall, there was a low CRM positive rates across all approach types to rectal resection with

restorative anastomosis (0 to 4.7%, Table 2). In unadjusted data for the low rectum, transanal
and robotic surgery had a the lowest positive margin rates rate than laparoscopic surgery (0/19
with a transanal perineal approach, and 1/27 with a non-transanal approach; (Table 6).

However, in a mixed-effects model (Table 7), none of the operative approaches were
significantly associated with margin positivity except for non-restorative surgery. The model
demonstrated good-fair discrimination (AUC: 0.72).

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Discussion

This study ~~identified~~ supports the use of ~~that a~~ TaTME approach for rectal cancer resection, ~~with~~ ~~has~~ comparable postoperative outcomes and ~~is~~ ~~oncological~~ ~~pathological~~ ~~ly~~ safety compared to other approaches. This is in line with recent evidence on TaTME delivery across Europe [12, 143-15]. The leak rate was higher than previously reported, at ~~12.9~~13.5%, which at univariable level was significantly higher than other techniques. Once adjusted for confounders, this variability was largely a result of anastomosis in the lowest part of the rectum; transanal surgery became non-significant in ~~multivariable~~ ~~mixed-effects~~ and propensity-score matched models. By including other techniques within this study, it allows individual surgeons and units to benchmark practice and consider their own selection of patients. TaTME was more commonly used in men, ~~in~~ those undergoing long course chemoradiotherapy and in those with low tumours. This parallels current recommendations for the selection of patients, ~~proving~~ ~~demonstrating appropriate adoption that implementation of this technique within included centres is safe~~ [5, 16].

Leak rates after transanal (TaTME) surgery have been reported as 4.7% ~~to~~ 9.1% in recent systematic reviews [5, 11] and 6.7% in a subsequent large international registry [17]. ~~We add to this literature by providing an unselected, 'real-world' view of implementation of TaTME internationally in a prospective setting, with risk-adjustment of outcome data with mixed-effects modelling.~~ The higher ~~unadjusted~~ leak rate identified in the present study may reflect learning curve effects from centres being at variable stages of adoption of the technique~~i~~. It may also reflect the fact that we only included malignant conditions. An important variability between studies still exists in how anastomotic leakage is defined and detected. By comparing leakage to a simultaneous cohort of laparoscopic, open and robotic resections from the same centres, we can explore and control for case selection variability by approach and mitigate against concerns of reporting bias. Reassuringly, male gender and low tumour height were strongly predictive

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factors for leak in our ~~multivariable mixed effects~~ models, which is consistent with current knowledge [18-20]. Whilst our data gives evidence for safety in the current dissemination of TaTME, structured training with proctorship from experienced proponents remains essential.

Improved ~~oncological pathological and oncological~~ outcomes ~~is~~ are a potential benefit of TaTME. The positive resection margin rate in restorative surgery from this study (4.04%) is consistent with previous reports, including the transanal component [5]. Ma et al previously reported a significantly lower difference rate of CRM involvement with TaTME when compared with laparoscopic TME [21]. In contrast, the Bordeaux randomized trial found a significantly greater rate of CRM involvement for laparoscopic TME when compared to TaTME (18.0% vs 4.0%, $p=0.025$) although this did not mean a decrease in local recurrence (long term oncological outcomes) [22]. The ~~lower~~ positive CRM rates seen with ~~TaTME and~~ robotic surgery in the lower rectum within the present study ~~are~~ likely to represent a degree of case selection at a site level; results from randomised trials in TaTME and robotic rectal cancer surgery are awaited.

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This study also provides valuable information for other resection techniques. Recent randomised trials have suggested laparoscopic TME may lack oncological safety compared to open surgery in the mid and low rectum (ALaCaRT and ACOSOG) [21, 22]. The present study shows ~~oncological pathological~~ equivalence of laparoscopic and open approaches, with a selection variability evident that suggests surgeons are carefully and correctly selecting patients for each approach; this is consistent with COLOR II, COREAN and CLASiCC trials [18, 19, 23]. There were relatively few robotic cases in this cohort. Where robotics was performed, the positive CRM and conversion rates were lower when compared to laparoscopic techniques. The ROLARR trial with 471 patients did not show differences between laparoscopic

and robotic for positive resection margin [24]. International registry studies alongside ROLARR reported a rate of conversion from laparoscopic to open or transanal of 6.3%. We found significant differences between laparoscopic transanal that presented the highest rate of conversion (16.2%) and robotic transanal (0%). This is consistent with the findings of ROLARR trial about the potential for robotic surgery to decrease the rate of conversion.

Finally the APER rate provides a contemporary permanent stoma rate across a variety of international sites for an operation with known variability between units [25]. Our group plans to produce a future report describing geographic variability in colorectal surgery, exploring differences in patient factors, disease presentations and techniques utilised internationally, across the last three international ESCP audits.

This study has limitations. Unadjusted outcomes showed higher major complication rates with robotic surgery and also transanal surgery, although without risk adjustment for confounding factors this must be interpreted with significant caution. Further research is needed to correctly risk-adjust for individual surgeon, or surgical team experience in TaTME, as well as unmeasured between-patient, tumour and operation-specific factors. Similarly, standardised definitions of anastomotic leakage and its detection remain uncommonly used between studies. Selection bias is an unavoidable factor in this type of observational research. We have attempted to minimize the effects of this by undertaking adjusted analyses using mixed-effects logistic regression models, but accept that this can never fully counteract the nuances involved in clinical decision-making. This said, the current study was designed to detect safety differences in current practice rather than test efficacy of treatments directly.

Results from randomised trials comparing outcomes after the variety of approaches available for rectal cancer surgery are now needed, particularly evaluating TaTME against laparoscopic ~~surgery~~-TME without a transanal perineal component [26].

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Authorship list (PubMed citable)

Writing Group

Aneel Bhangu (First author), [Ana María Minaya-Bravo](#)~~Ana Minaya~~, Gaetano Gallo, James C Glasbey, Sivesh Kamarajah, Thomas Pinkney, Alaa El-Hussana (Chair)

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Collaborators

[Albania: S. Bilali, V. Bilali \(University Hospital Center Mother Teresa\).](#)

[Argentina: M. Salomon, M. Cillo, D. Estefania, J. Patron Uriburu, H. Ruiz \(Buenos Aires British Hospital\); P. Farina, F. Carballo, S. Guckenheimer \(Hospital Pirovano\).](#)

Australia: D. Proud, R. Brouwer, A. Bui, B. Nguyen, P. Smart (Austin Hospital); A. Warwick, J. E. Theodore (Redcliffe Hospital).

Austria: F. Herbst, T. Birsan, B. Dauser, S. Ghaffari, N. Hartig (Barmherzige Brueder, Wien); A. Stift, S. Argeny, L. Unger (Medical University of Vienna); R. Strouhal, A. Heuberger (Oberndorf b. Salzburg).

Belarus: A. Varabei, N. Lahodzich, A. Makhmudov, L. Selniahina (Minsk Regional Clinical Hospital).

Belgium: T. Feryn, T. Leupe, L. Maes, E. Reynvoet, K. Van Langenhove (AZ Sint-Jan Brugge); M. Nachtergaele (AZ St Jozef); B. Monami, D. Francart, C. Jehaes, S. Markiewicz, J. Weerts (Clinique St Joseph, Liege); K. Van Belle, B. Bomans, V. Cavenaile, Y. Nijs, M. Vertruyen (Europe Hospitals Brussels); P. Pletinckx, D. Claeys, B. Defoort, F. Muysoms, S. Van Cleven (Maria Middelaes Gent); C. Lange, K. Vindevoghel (OLV van Lourdes Hospital Waregem); A. Wolthuis (University Hospital Leuven).

Bosnia and Heregovina: M. Todorovic, S. Dabic, B. Kenjic, S. Lovric, J. Vidovic (JZU Hospital Sveti Vračevi); S. Delibegovic, Z. Mehmedovic (University Clinic Center Tuzla).

Brazil: A. Christiano, B. Lombardi, M. Marchiori Jr, V. Terciotti Jr (Hospital Centro Médico de Campinas).

Bulgaria: D. Dardanov, P. Petkov, L. Simonova, A. Yonkov, E. Zhivkov (Alexandrovska Hospital - First Surgery); S. Maslyankov, V. Pavlov, M. Sokolov, G. Todorov (Alexandrovska Hospital, Second Surgery Clinic); V. Stoyanov, I. Batashki, N. Iarumov, I. Lozev, B. Moshev (Medical

Institute - Ministry of Interior); M. Slavchev, B. Atanasov, N. Belev, P. Krstev, R. Penkov (University Hospital - Eurohospital).

Croatia: G. Šantak, J. Ćosić, A. Previšić, L. Vukušić, G. Zukanović (County Hospital Požega); M. Zelić, D. Kršul, V. Lekić Vitlov, D. Mendrila (University Hospital Rijeka).

Czech Republic: J. Orhalmi, T. Dusek, O. Maly, J. Paral, O. Sotona (Charles University Hospital). M. Skrovina, V. Bencurik, M. Machackova (Complex Oncology Centre Nový Jičín, Surgical Department); Z. Kala, M. Farkašová, T. Grolich, V. Procházka (Surgical Department, University Hospital Brno); J. Hoch, P. Kocian, L. Martinek (University Hospital Motol, Prague); F. Antos, V. Pruchova (University Hospital Prague Bulovka).

Denmark: A. El-Hussuna, A. Ceccotti, T. Madsbøll, D. Straarup, A. Uth Ovesen (Aalborg University Hospital); P. Christensen, P. Bondeven, P. Edling, H. Elfeki, V. Alexandrovich Gameza, S. Michelsen Bach, I. Zheltiakova (Aarhus University Hospital/Randers Regional Hospital); PM. Krarup, A. Krogh, H-C. Rolff (Bispebjerg); J. Lykke, A. F. Juvik, H. H. K. Lóven, M. Marckmann, J. T. F. Osterkamp (Herlev Hospital); A. H. Madsen, J. Worsøe (Hospital Unit West); A. Ugianskis (North Denmark Regional Hospital); M. D. Kjær, B. Youn Cho Lee (Odense University Hospital); A. Khalid, M. H. Kristensen (Regional Hospital Viborg).

Egypt: M. El Sorogy, A. Elgeidie, M. Elhemaly, A. El Nakeeb, M. Elrefai (Gastrointestinal Surgery Center, Mansoura University); M. Shalaby, S. Emile, W. Omar, A. Sakr, W. Thabet (Mansoura University Hospital); S. Awany, I. Metwally, B. Refky, N. Shams, M. Zuhdy (Oncology Center Mansoura University).

Finland: A. Lepistö, I. Keränen, A. Kivelä, T. Lehtonen, P. Siironen (Helsinki University Hospital); T. Rautio, M. Ahonen-Siirtola, K. Klintrup, K. Paarnio, H. Takala (Oulu University

Hospital); M. Hyöty, E. Haukijärvi, S-M. Kotaluoto, K. Lehto, T. Tomminen (Tampere University Hospital); H. Huhtinen, A. Carpelan, J. Karvonen, A. Rantala, P. Varpe (Turku University Hospital).

France: E. Cotte, Y. Francois, O. Glehen, G. Passot (Centre Hospitalier Lyon Sud); A. d'Alessandro, E. Chouillard, J. C. Etienne, E. Ghilles, B. Vinson-Bonnet (Centre Hospitalier Poissy Saint Germain en LayeCHIPS); A. Germain, A. Ayav, L. Bresler (CHU Nancy-Brabois); R. Chevalier, Q. Denost, R. Didailler, E. Rullier (Hopital Haut Leveque); E. Tiret, N. Chafai, J. H. Lefevre, Y. Parc (Hôpital Saint-Antoine); I. Sielezneff, D. Mege (Timone Hospital); Z. Lakkis (University Hospital of Besancon); M. Barussaud (University Hospital of Poitiers).

Germany: C. Krones, B. Bock, R. Webler (Marienhospital Aachen); J. Baral, T. Lang, S. Münch, F. Pullig, M. Schön (Städtisches Klinikum Karlsruhe); S. Hinz, T. Becker, T. Möller, F. Richter, C. Schafmayer (University Hospital Schleswig-Holstein, Kiel); J. Hardt, P. Kienle (University Medical Center Mannheim); F. Crescenti, M. Ahmad, Y. Soleiman (Verden KRH).

Greece: I. Papaconstantinou, A. Gklavas, K. Nastos, T. Theodosopoulos, A. Vezakis (Areteion Hospital); K. Stamou, A. Saridaki (Athens Bioclinic); E. Xynos, S. Paraskakis, N. Zervakis (Creta-InterClinic Hospital); G. Skroubis, T. Amanatidis, S. Germanos, I. Maroulis, G. Papadopoulos (General University Hospital of Patras); N. Dimitriou, A. Alexandrou, E. Felekouras, J. Griniatsos, I. Karavokyros (Laiko Hospital); A. Papadopoulos, C. Chouliaras, P. Ioannidis, D. Katsounis, E. Kefalou (Nikaia General Hospital); I. E. Katsoulis, D. Balalis, D. P. Korkolis, D. Manatakis (St. Savvas Cancer Hospital); G. Tzovaras, I. Baloyiannis, I. Mamaloudis (University Hospital of Larissa).

Hungary: G. Lázár, S. Ábraham, A. Paszt, Z. Simonka, I. Tóth (Department of Surgery, University of Szeged); A. Zaránd, Z. Baranyai, G. Ferreira, L. Harsányi, P. Ónody (Semmelweis

University, 1st Clinic of Surgery); B. Banky, Á. Burány, M. Lakatos, J. Marton, A. Solymosi (St. Borbala Hospital); I. Besznyák, A. Bursics, G. Papp, G. Saftics, I. Svastics (Uzsoki Hospital);

Iceland: E. Valsdottir, J. Atladottir, T. Jonsson, P. Moller, H. Sigurdsson (University Hospital of Iceland).

India: S. K. Gupta, S. Gupta, N. Kaul, S. Mohan, G. Sharma (Government Medical College, Jammu, Jammu and Kashmir, India); R. Wani, N. Chowdri, M. Khan, A. Mehraj, F. Q. Parray (Sher-i-Kashmir Institute of Medical Sciences).

Ireland: A. Coveney, J. Burke, J. Deasy, S. El-Masry, D. McNamara (Beaumont Hospital); M. F. Khan, R. Cahill, E. Faul, J. Mulsow, C. Shields (Mater Misericordiae University Hospital); M. E. Kelly, G. Bass, S. T. Martin, R. O'Connell, E. Ryan (St Vincent's Private Hospital); T. Connelly, G. Ahmad, W. Bukhari, F. Cooke (University Hospital Waterford).

Israel: O. Zmora, R. Gold Deutch, N. Haim, R. Lavy, A. Moscovici (Assaf Harofe Medical Center); N. Shussman, R. Gefen, G. Marom, A. Pikarsky, D. Weiss (Hadassah Hebrew University Medical Center); S. Avital, N. Hermann, B. Raguan, M. Slavin, I. White (Meir Medical Center); N. Wasserberg, H. Arieli, N. Gurevich (RMC, Beilinson Campus); M. R. Freund, S. Dorot, Y. Edden, G. Halfteck, P. Reissman, ~~E. Yair~~ (Shaare Zedek ~~Mount Sinai~~ Medical Center); Y. Edden, R. Pery (Sheba Medical Center); H. Tulchinsky, A. Weizman (Sourasky Medical Center).

Italy: F. Agresta, R. Curinga, E. Finotti, G. Savino, L. A. Verza (Adria Hospital); C. R. Asteria, L. Boccia, A. Pascariello (ASST - Mantua); N. Tamini, A. Bugatti, L. Gianotti, M. Totis (Asst-Monza, Ospedale San Gerardo); L. Vincenti, V. Andriola, I. Giannini, E. Travaglio (Azienda

Ospedaliero Universitaria Consorziale Policlinico di Bari); R. Balestri, P. Bucciatti, N. Roffi, E. Rossi, L. Urbani (Azienda Ospedaliero Universitaria Pisana); A. Mellano, A. Cinquegrana (Candiolo Cancer Institute IRCCS); A. Lauretta, C. Belluco (Chirurgia Oncologica Generale, IRCCS Centro di Riferimento Oncologico, Aviano ~~Centro di Riferimento Oncologico, IRCCS, Aviano~~); M. Mistrangelo, M. E. Allaix, S. Arolfo, M. Morino, V. Testa (Citta della Salute e della Scienza di Torino); P. Delrio, U. Pace, D. Rega, D. Scala (Division of Colorectal Surgery, Department of Abdominal Surgery, Istituto Nazionale Tumori "Fondazione G.Pascale ", IRCCS Naples ~~Colorectal Surgical Oncology Istituto Nazionale per lo Studio e la Cura dei Tumori~~); G. Gallo, G. Clerico, S. Cornaglia, A. Realis Luc, M. Trompetto (Department of Colorectal Surgery, S. Rita Clinic); G. Ugolini, N. Antonacci, S. Fabbri, I. Montroni, D. Zattoni (Faenza Hospital); C. D'Urbano, A. Cornelli, M. Viti (G. Salvini); M. Inama, M. Bacchion, A. Casaril, H. Impellizzeri, G. Moretto (Hospital Dott. Pederzoli); A. Spinelli, M. Carvello, G. David, F. Di Candido, M. Sacchi (Humanitas Research Hospital); A. Frontali, V. Ceriani, M. Molteni (IRCCS MultiMedica); R. Rosati, F. Aleotti, U. Elmore, M. Lemma, A. Vignali (IRCCS San Raffaele, Department of Gastrointestinal Surgery ~~IRCCS Ospedale San Raffaele~~); S. Scabini, G. Casoni Pattacini, A. Luzzi, E. Romairone (Policlinico ~~IRCCS San Martino, Genoa-IST~~); F. Marino, D. Lorusso, F. Pezzolla (Dept. of General Surgery, IRCCS "Saverio de Bellis", Castellana Grotte (Ba) ~~IRCCS 'Saverio de Bellis'~~); F. Colombo, C. Baldi, D. Foschi, G. Sampietro, L. Sorrentino (L. Sacco University Hospital); S. Di Saverio, A. Birindelli, E. Segalini, D. Spacca (Maggiore Hospital); G. M. Romano, A. Belli, F. Bianco, S. De franciscis, A. Falato (Surgical Oncology Istituto Nazionale Tumori G.Pascale ~~National Cancer Institute~~ Naples); A. Muratore, P. Marsanic (Ospedale Agnelli Pinerolo); S. Grimaldi, N. Castaldo, M. G. Ciolli, P. Picarella, R. Porfidia (Ospedale Convenzionato Villa dei Fiori Acerra); S. Di Saverio, A. Birindelli, G. Tugnoli (Ospedale Maggiore); A. Bondurri, D. Cavallo, A. Maffioli, A. Pertusati (Ospedale Sacco Italy); F. Pulighe, F. Balestra, C. De Nisco, M. Podda (Ospedale San Francesco); E. Opocher, M. Longhi, N. M. Mariani, N. Maroni, A. Pisani Ceretti (Ospedale San Paolo); R. Galleano, P. Aonzo, G. Curletti,

L. Reggiani (Ospedale Santa Corona); M. Marconi, L. Del Prete, M. Oldani, R. Pappalardo, S. Zaccone I (Ospedale Santa Maria delle Stelle); M. Scatizzi, M. Baraghini, S. Cantafio, F. Feroci, I. Giani (Ospedale Santo Stefano, Prato); R. Tutino, G. Cocorullo, G. Gulotta, L. Licari, G. Salamone (Policlinico 'P. Giaccone'); P. Sileri, F. Saraceno (Policlinico Tor Vergata); F. La Torre, P. Chirletti, D. Coletta, G. De Toma, A. Mingoli (Policlinico Umberto I 'Sapienza University'); M. Papandrea, E. De Luca, R. Sacco, G. Sammarco, G. Vescio (Policlinico Universitario di Catanzaro); V. Tonini, S. Bianchini, M. Cervellera, S. Vaccari (Policlinico universitario Sant'Orsola-Malpighi, Universita degli Studi di Bologna); N. Cracco, G. Barugola, E. Bertocchi, R. Rossini, G. Ruffo (Sacro Cuore Don Calabria Hospital); A. Sartori, N. Clemente, M. De Luca, A. De Luca, G. Scaffidi (San Valentino Hospital); L. Lorenzon, G. Balducci, T. Bocchetti, M. Ferri, P. Mercantini (Sant'Andrea Hospital); F. Pata, S. Bause, A. Benevento, C. Bottini, P. R. Crapa (Sant' Antonio Abate Hospital, Gallarate); M. Rubbini, G. Anania, P. Carcoforo, G. Cavallesco, C. Feo (University Hospital of Ferrara).

Japan: T. Yamamoto (Yokkaichi Hazu Medical Centre).

Latvia: A. Sivins, G. Ancans, S. Gerkis, R. Lunis, A. Pcolkins (Latvia Oncology Center).

Lithuania: D. Venskutonis, S. Bradulskis, E. Dainius, A. Subocius, J. Vencius (Department of General Surgery, LSMU, Kaunas Clinical Hospital); P. Zeromskas, V. Eismiontas, V. Nutautiene, D. Simcikis, A. Tamosiunas (Klaipeda University Hospital); S. Svagzdys, T. Latkauskas, P. Lizdenis, Z. Saladzinskas, A. Tamelis (Lithuanian University of Health Sciences Hospital Kauno Klinikos); A. Dulskas, J. Kuliavas, N. E. Samalavicius (National Cancer Institute, Lithuania); T. Poskus, V. Jotautas, S. Mikalauskas, E. Poskus, K. Strupas (Vilnius University).

Malaysia: A. D. Zakaria, N. N. Lah, M. Wong, W. Z. Zain, Z. Zakaria (Department of Surgery, School of Medical Sciences, ~~Hospital~~ Universiti Sains Malaysia / Hospital Universiti Sains Malaysia); L. Mazlan, Z. A. Mohd Azman, I. Sagap (UKM Medical Centre).

Malta: J. Psaila, P. Andrejevic, C. Cini, S. Ellul, K. Pace (Mater Dei Hospital). Morocco: M. Ahallat, M. Hamid, A. Hrra, M. A. Majbar, M. Raiss (Ibn Sina University Hospital).

Netherlands: E. Westerduin, W. Bemelman, C. Buskens, P. Tanis (Academic Medical Centre); P.C. van der Sluis, P.H. Davids, A. Pronk, A.H.W. Schiphorst, N. Smakman (Diakonessenhuis); D. Zimmerman, T. Koeter, J. Stijns, Y-T. van Loon (Elisabeth TweeSteden Hospital); M. Vermaas, E. de Graaf, P. Doornebosch, P. van Hagen, O. van Ruler (Ijsselland Ziekenhuis); B. Toorenvliet, J. Nonner, I. van den Berg, L. van Steensel, W. Vles (Ikazia); J. Melenhorst, R. Orsini, R. Visschers (Maastricht University Medical Centre); C. Hoff (Medical Center Leeuwarden); R. Blom, H. Marsman (Onze Lieve Vrouwe Gasthuis); I. Mulder, H. Cense, S. de Castro, A. Demirkiran, M. Hunfeld (Rode Kruis Ziekenhuis Beverwijk); A. van Geloven, J. de Groof, E. Hendriks, M. Leeuwenburg, N. van Oorschot (Tergooi); F. Wit, C. Rupert, P. Veldman (Tjongerschans ziekenhuis); M. Keijzers, J. Konsten (VieCuri Medisch Centrum voor Noord Limburg); F. Den Boer, M. Corver (Zaans Medical Center); E. G. ~~J.~~ Boerma, L. Koolen, M. Martens, K. Van Wijck (Zuyderland Medical Center).

Norway: D. Ignjatovic, R. Breuer, B. Gurpreet, T. Oresland, T. Tetens Moe (Akershus University Hospital); A. Nesbakken, I. Flaaten ~~h~~ Backe, T-A. Wik (Oslo University Hospital); K. Radiya, T. Dehli, P. Gjessing, S. Norderval, K. Woll (University Hospital of North Norway).

Pakistan: M. Anwer, M. S. Qureshi (JPMC WARD 2); A. U. Qureshi, M. Billah, M. Y. Jawad, A. Raza, N. Urooj (King Edward Medical University/Mayo Hospital, Lahore).

People's Republic of China: X. Wang, L. Li (West China Hospital in Sichuan University). Poland: D. Jajtner, B. Gasinski, W. Kabiesz (Beskidian Oncology Center); P. Walega, M. Romaniszyn (Third Department of General Surgery, Jagiellonian University Medical College); M. Zawadzki, R. Czarnecki, Z. Obuszko, M. Rzaca, M. Sitarska (Wojewódzki Szpital Specjalistyczny).

Portugal: P. Silva, A. Duarte, D. Gonçalves, M. Morais (Centro Hospitalar de S. João); N. Rama, J. Nobre, I. Sales (Centro Hospitalar Leiria, EPE); J. Costa Pereira, S. Costa, C. Costa Pereira, C. Insua, I. Romero (Centro Hospitalar Tâmega e Sousa); N. Figueiredo, J. Cunha, H. Domingos, P. Vieira (Champalimaud Foundation); M. Cunha, M. Americano, E. Amorim, J. Rachadell (Cirurgia 2 - CHA - Unidade Portimão); J. M. Carvas, I. Armas, P. Fernandes, C. Pires, R. Reis (Hospital de Bragança); R. Martins, M. Dos Santos, P. Henriques (Hospital de Faro, Centro Hospitalar do Algarve); O. Oliveira, M. Duarte, L. Ferreira, J. Miranda, N. Vilela (Hospital Distrital de Santarém, E.P.E.); J. Corte Real, S. Carlos, M. Frois Borges, P. Moniz Pereira, J. Simões (Hospital Garcia de Orta); P. Silva-vaz, V. Bettencourt, A. Gouveia, H. Perez, R. Rainho (Unidade Local de Saúde de Castelo Branco).

Romania: V. Bintintan, C. Ciuce, G. Dindelegan, R. Scurtu, R. Seicean (Clinica Chirurgie I); D. Cristian, T. Burcos, F. Grama, D. M. Mandi, G. Richiteanu (Coltea Clinical Hospital); A. Miron, V. Calu, O. Enciu, M. Nadragea, R. Parvuletu (Elias Emergency Hospital); S. S. Mogoanta, A. Crafcuic, S. Paitici (Emergency County Hospital of Craiova); I. Negoï, M. Beuran, C. Ciubotaru, A. Prodan, M. Vartic (Emergency Hospital of Bucharest); V. Tomulescu, C. Copaescu (Ponderas Academic Hospital).

Russia: A. Yanishev, A. Abelevich, A. Kokobelyan, M. Lebedeva, R. Luzan (FSBEI HE PRMU MOH); D. Popov, A. Sednev, A. Klimenko, A. Semenov, S. Vasilyev (City Hospital 9); A. Pozdnyakov, D. Cherdancev, D. Mahotin, A. Nesytkh, V. Samsonyuk (Krasnoyarsk Regional

Clinical Hospital); I. Pravosudov, D. Ivlev, A. Karachun, K. Lebedev, D. Samsonov (N.N. Petrov National Medical Research Institute Center of Oncology); R. Aiupov, D. Feoktistov, M. Garipov, S. Nail, N. Tarasov (National Republic Oncology Center); A. Yanishev, A. Abelevich, A. Kokobelyan, M. Lebedeva, R. Luzan (Nizhny Novgorod Regional Clinical Hospital); R. Aiupov, D. Feoktistov, M. Garipov, N. Suleymanov, N. Tarasov (Republican Oncological Centre, Ufa); A. Rasulov, H. Dzhumabaev, Z. Mamedli (Russian Cancer Research Center); A. Bedzhanyan (Russian Research Center of Surgery named after B.V.Petrovsky); D. Popov, A. Sednev, A. Klimenko, A. Semenov, S. Vasilyev (Saint-Petersburg City Hospital 9); A. Khazov, M. Khanevich, G. Khrykov (Saint-Petersburg Clinical Oncological Health Center); S. Katorkin, P. Andreev, A. Chernov, O. Davidova, A. Zhuravlev (Samara State Medical University); S. Achkasov, D. Shakhmatov, Y. Shelygin, O. Sushkov, A. Vardanyan (State Scientific Centre of Coloproctology); A. Ilkanich, N. Barbashinov, V. Darvin, S. Onishchenko, Y. Voronin (Surgut District Hospital).

Serbia: Z. Krivokapić, G. Barišić, I. Dimitrijević, V. Marković, A. Sekulić (Clinic for Digestive Surgery-First Surgical Clinic, Clinical Center of Serbia, University of Belgrade, Medical Faculty); G. Stanojevic, B. Brankovic, M. Nestorovic, V. Pecic, D. Petrovic (Clinic for General Surgery, Clinical Center Nis); I. Kostic, A. Aleksic, D. Dabic, B. Maric, V. Perunicic (General Hospital Cacak); Z. Radovanovic, M. Djuric, D. Lukic, D. Radovanovic (Oncology Institute of Vojvodina); V. Cuk, V. Cuk, J. Juloski, M. Kenic, I. Krdzic (Surgical Clinic KBC Zvezdara).

Singapore: J. C. Ngu, Y. Y. Ng, N. Teo (Changi General Hospital).

Slovak Republic: J. Korcek, A. Lazorisak, (Faculty Hospital Nitra).

Slovenia: M. Rems, Š. Ramovš Trampuš (General Hospital Jesenice); A. Tomazic, J. Grosek, J. Kosir, G. Norcic (University Medical Centre Ljubljana).

Spain: V. Vigorita, N. Caceres, E. Casal, A. Ruano, I. Trostchansky (Alvaro Cunqueiro Hospital); T. Golda, A. Galvez Saldaña, E. Kreisler Moreno, J. Lopez Dominguez, M. Vila Tura (Bellvitge University Hospital); F. Labarga, P. Galvez, V. Maderuelo, C. Suero (Complejo Asistencial Universitario de Palencia); J. Bargallo, L. Cayetano, S. Lamas, M. C. Silva (Consorti Sanitari de Terrassa - Hospital de Terrassa); J. C. Bernal-Sprekelsen, R. Gómez, S. Jareño, A. Ríos, D. Vercher (Consortio Hospital General Universitario); J-M. García-González, J. Cervera-Aldama, J. Ramos-Prada, M. Santamaría-Olabarrieta (Cruces University Hospital); N. Borda, J. M. Enríquez-Navascués, Y. Saralegui (Donostia University Hospital); A. Calero-Lillo, S. Aznar-Puig, M. A. López-Lara, S. Muñoz-Collado, J. Valverde-Sintas (Fundacio Hospital Esperit Sant); P. Menendez, C. Leon (Gutierrez Ortega Hospital); N. Truan, R. Baldonado, D. Fernández-Martínez, J. Otero, L. Solar-García (Hospital Universitario Central de Asturias); V. Turrado-Rodriguez, F. de Lacy Oliver, A. M. Lacy Fortuny, B. Martin Perez, A. M. Otero Piñeiro (Hospital Clinic Barcelona); J. Paredes, F. Fernandez, M. J. Ladra, A. Paulos, D. Prieto (Hospital Clinico Universitario de Santiago de Compostela); J. P. Beltrán de Heredia, F. Blanco Antona, B. de Andrés Asenjo, C. Ferreras García, A. Romero de Diego (Hospital Clínico Universitario de Valladolid); E. Cordoba Diaz de Laspra, E. Echazarreta Gallego, M. Elia Guedea (Hospital Clinico Universitario de Zaragoza); D. Escola, S. Martinez (Hospital Comarcal Alt Penedes); V. Primo Romaguera, R. Parreño, L. Pastor, E. Rosell (Hospital de Dénia); R. Lozoya Trujillo, R. Alós Company, M. D. Ruiz Carmona, A. Solana Bueno (Hospital de Sagunto); S. Salvans Ruiz, S. Alonso Gonçalves, M. Jiménez- Toscano, M. Pascual Damieta, M. Pera Roman (Hospital Del Mar); E. M. Pellicer-Franco, J. A. Garcia-Marin, M. Mengual-Ballester, V. Soria-Aledo, G. Valero-Navarro (Hospital Morales Mesequer); M. Vicente-Ruiz, C. Garcia-Zamora, A. Gonzalez-Gil, M. J. Montoya-Tabares, M. Paredes-Quiles (Hospital Rafael

Mendez); J. Die Trill, P. Abadia, I. Moreno, J. D. Pina, D. Ramos Rubio (Hospital Ramon y Cajal); J. Escartin, J. L. Blas, J. Fernando, R. Ferrer, J. Garcia Egea (Hospital Royo Villanova); I. Pros, W. Martinez, J. Rius, M. Socías (Hospital Sant Joan de Deu de Martorell); D. Sabia, J. Castellvi Valls, V. Gonzalez Santin, S. Mompert Garcia, L. Viso Pons (Hospital Sant Joan Despi Moises Broggi); D. Julià, A. Codina-Cazador, R. Farrés, N. Gómez, P. Planellas (Hospital Universitari de Girona Doctor Josep Trueta); M. Cuadrado, I. Camps (Hospital Universitari Germans Trias I Pujol); M. Rufas, J. Escoll, A. Fermiñán, P. Muriel, E. Sierra (Hospital Universitario Arnau de Vilanova de Lerida); C. Alvarez-Laso, P. Lora, H. Padin (Hospital Universitario de Cabueñes); J. Garcia-Septiem, C. Bustamante, V. Jimenez, J. Jimenez-Miramón, J. L. Ramos (Hospital Universitario de Getafe); A. B. Gallardo, P. Benito, L. Colao, P. Galindo, C. Garcia (Hospital Universitario de Torrejón de Ardoz); A. Forero-Torres, A. Alonso Poza, B. Dieguez Fernandez, C. Gilsanz Martin, M. Hernandez Garcia (Hospital Universitario del Sureste); J. A. Rojo López, J. M. Gil López, M. González Zunzárrén, J. Martínez Alegre, L. J. P. Zorrilla Matilla (Hospital Universitario Infanta Sofia); A. Navarro-Sánchez, F. J. Alcalá Serrano, J. López-Fernández, D. Montesdeoca Cabrera (Hospital Universitario Insular de Gran Canaria); M. Alvarez-Gallego, J. Guevara, I. Pascual Miquelañez, I. Rubio-Perez (Hospital Universitario La Paz); M. Gomez Ruiz, J. Alonso Martín, C. Cagigas Fernández, J. Castillo Diego (Hospital Universitario Marques de Valdecilla); J. A. Pando, C. Maristany, A. Muñoz-Duyos, A. Rada-Palomino, H. Vargas-Pierola (Hospital Universitario Mutua Terrassa); E. Peña Ros, J. A. Benavides Buleje, J. M. Muñoz Camarena, P. A. Parra Baños, M. Ramirez Faraco (Hospital Universitario Reina Sofía); J. J. Arenal, M. A. Citores, J. L. Marcos, J. Sánchez, C. Tinoco (Hospital Universitario Río Hortega); L. J. García Flórez, R. D. Arias Pacheco, G. Mínguez Ruiz, N. Gutiérrez Rodríguez Corral, A. Rodríguez Infante (Hospital Universitario San Agustín); M. J. Carrillo López, M. M. Carrasco Prats, A. Lage Laredo, Á. Martínez Manzano, P. Rodríguez García (Hospital Universitario Santa Lucia); J. J. Segura-Sampedro, N. Alonso-Hernández, M. Fernandez Isart, M. Gamundi Cuesta, A. Ochogavia Segui (Hospital

Universitario Son Espases); N. Ibañez, J. Abrisqueta, J. Lujan (Hospital Universitario Virgen de la Arrixaca); R. Gómez Pérez, E. Corrales Valero, C. Monje Salazar, E. Sanchiz Cardenas, R. Soler Humanes (Hospital Universitario Virgen de la Victoria); R. M. Jimenez-Rodriguez, F. De la Portilla, J. M. Diaz Pavon, A. M. Garcia Cabrera, M. L. Reyes Diaz (Hospital Universitario Virgen del Rocío); E. Espin, F. Marinello, M. Martí, J. L. Sanchez, F. Vallribera (Hospital Valle de Hebron); F. J. Orts Mico, M. Ortin Navarro, M. Perez Climent, C. Serra Diaz (Hospital Virgen de los Lirios); M. Millan, A. Caro, J. Escuder, B. Espina, F. Feliu (Joan XXIII University Hospital); A. Climent Aira, A. Estévez Diz, M. T. Moreno Asencio, A. Varela Mato, R. Vázquez Bouzán (POVISA Hospital); A. M. Minaya-Bravo, M.M. Diez-Alonso, R. Villeta-Plaza (Principe de Asturias Hospital); H. Guadalajara, D. Alías, D. García Olmo, C. Pastor, I. Valverde (Quironsalud Publicos); A. Sanchez Romero, A. Gardea, M. Gil Santos, T. Nimmersgern, P. Serrano Paz (Unidad de Coloproctologia, Hospital Vinalopó-Torre Vieja); M. Romero-Simó, T. Blasco-Segura, I. Caravaca-García, D. Costa-Navarro, A. Zarco-Pleguezuelos (University General Hospital of Alicante); L. Sánchez-Guillén, B. Flor-Lorente, M. Frasson, Á. García-Granero, E. García-Granero (University Hospital La Fe Valencia); B. Arencibia, J. Alonso, G. Febles, E. M. Nogués, C. Roque (University Hospital of Gran Canaria Dr. Negrín).

Sweden: J. Segelman, J. Nygren (Ersta Hospital); G. Nestler (Falu lasarett); M. Abraham-Nordling, M. Egenvall (Karolinska University Hospital); P. Myrelid, B. Jung, P. Loftås (Linköping University Hospital); M-L. Lydrup, N. Azahr, P. Buchwald, P. Mangell, I. Syk (Skane University Hospital); M. Nikberg, J. Carlander, A. Chabok, K. Smedh, C. Tiselius (Västmanlands Hospital Västerås); S. Haapaniemi, A. Benckert (Vrinnevi Hospital Norrköping).

Switzerland: M. Adamina, C. Freil-Lanter, C. Gingert, P. Müller, J. Schäfli (Kantonsspital Winterthur); L. Regusci, M. Brenna, F. Fasolini (Regional Hospital Mendrisio); H. Misteli, P. Kirchhoff, D. Oertli (University Hospital Basel, Switzerland); D. Hahnloser, D. Clerc, M. Hübner

(University Hospital of Lausanne, CHUV); F. Ris, N. C. Buchs, M. Chevallay, P. Morel, B. Schiltz (University Hospitals Geneva).

Taiwan: J. Y. Wang, W-C. Su, C-W. Huang, C-J. Ma, H-L. Tsai (Kaohsiung Medical University Hospital).

Turkey: ~~G. S. Özbacı, B. B. Özkan, U. Karabacak (19 Mayıs University Faculty of Medicine); D. Bugra (American Hospital); F. Agalar, H. Baloglu, I. Basoglu (Anadolu Medical Center [in aff with Johns Hopkins Med]); N. Okkabaz, E. Binboga, A. Biricik, A. Celik, E. Yavuz (Bagcilar Training and Research Hospital); A. E. Canda, C. Agalar, M. Fuzun, S. Sokmen, C. Terzi (Dokuz Eylul University); A. Isik (Erzincan University, Mengucek Gazi Training and Research Hospital); B. Karip, A. C. Bilgili (Fatih Sultan Mehmet Training and Research Hospital); S. Leventoglu, B. Aytac, E. Küçükdiler, A. Yıldız, O. Yuksel (Gazi University Medical School); H. Sinan, O. Hancerliogullari, S. Kaymak, O. Kozak, M. T. Ozer (Gulhane Training and Research Hospital); I. S. Sarici, O. Akca, M. U. Kalayci, Y. Kara (Kanuni Sultan Suleyman Training and Research Hospital); D. Bugra, O. Agcaoglu, E. Balik, O. Bayram (Koc University School of Medicine); G. S. Özbacı, B. B. Özkan, U. Karabacak (On Dokuz Mayıs University Faculty of Medicine); U. Sungurtekin, U. Ozgen (Pamukkale University School of Medicine); S. Demirbas (TOBB-ETU University Hospital); E. Öztürk, O. Isik, T. Yilmazlar (Uludag University School of Medicine); E. Colak, S. Karagul, V. Kinas (University of Health Sciences, Samsun Training and Research Hospital).~~

UK: N. Fearnhead, I. Lord, P. Stewart (Addenbrooke's [Cambridge University] Hospital); M. Zammit (Basildon Hospital); S. Arnold, N. J. Battersby, J. Broadhurst, ~~A. Mehta~~ S. Moran, F. Seretis (Basingstoke and North Hampshire Hospital); J. Shabbir, C. Jones, J. Kynaston (Bristol Royal Infirmary); D. Vimalachandran, E. Blower, C. McFaul, D. McWhirter, J. Pilkington

(Countess of Chester Hospital); T. Wilson, M. Chowdhary (Doncaster Royal Infirmary); B. Stubbs, M. Abdalkoddus, C. Lai, N. Thavanesan, C. Yao (Dorset County Hospital); T. Agarwal, S. Dindyal, R. M. C. Hill, S. Reade, A. Slesser (Ealing Hospital); H. Paterson, A. Balfour, M. Boland, A. Geraghty, J. O'Kelly (Edinburgh Western General Hospital); P. Patel, S. Tezas (Furness General Hospital); S. Yahia, V. Jadhav, K. Marimuthu, A. Narayanan, B. Piramanayagam (George Eliot Hospital); N. Bradley, F. Buchanan, K. Paul, J. Singh, K. Thomson (Glasgow Royal Infirmary); S. Korsgen, M. Bedford, K. Lee, K. Leong (Good Hope Hospital); D. McArthur, A. Bhangu, S. Malik, I. Mohamed (Heartlands Hospital); P. Cunha, A. Pilavas (Homerton University Hospital NHS Trust); A. Reddy, S. Ahmed, A. Ahmed, J. Voll (James Cook University Hospital); V. Velchuru, R. Lal, B. Mirshekar-Syahkal (James Paget Hospital); M. Kassai, M. Aleem, S. Keogh-Bootland (Jersey General Hospital); P. Sarmah, S. Brown, R. Keegan, A. Kelkar, P. Sen (Kettering General Hospital); M. Oliveira-Cunha, S. Chaudhri, R. Fares, B. Singh, W. M. Thomas (Leicester General Hospital); M. I. Aslam, K. Boyle, D. Hemingway, A. Miller, M. Norwood (Leicester Royal Infirmary); S. Gurjar, M. Al-Saeedi, L. Anandan, A. Sudlow, N. Zampitis (Luton & Dunstable Hospital); K. Malik, M. Bogdan, C. Smart (Macclesfield District General Hospital); M. R. Iqbal, S. Bailey, D. Lawes, G. Omar, R. Tamhane (Maidstone and Tunbridge Wells NHS Trust); M. Evans, S. Ather, J. Lim, H. Nageswaran, G. Taylor (Morrison Hospital); L. Hunt, J. Nicholls (Musgrove Park Hospital); I. Shaikh, F. Muscara, J. O'Brien, E. Photi, A. Stearns (Norfolk and Norwich University Hospital); D. Meylemans, C. Cunningham, R. Hompes (Oxford University Hospitals); A. Tennakoon, N. Kumarasinghe, M. Rao, I. Upanishad (Pilgrim Hospital); ~~S. Smolarek, E. Platt, B. Rossi, J. C. Tham (Plymouth Hospital NHS Trust);~~ J. Khan, N. Ahmad, Z. Shweejawee, S. Stefan (Queen Alexandra Hospital); N. Smart, I. Daniels, T. Gregoir, L. Longstaff, F. McDermott (Royal Devon & Exeter Hospital); M. Varcada, I. Dami, T. Gala, E. Moggia, K. Ratnatunga (Royal Free Hospital NHS Trust Hampstead); R. Harries, J. Hayes, G. Williams (Royal Gwent Hospital); T. Raymond, C. Bronder, E. Davies, P. Hawkin, O. Ryska (Royal Lancaster Infirmary); K. Ayral, A.

Beveridge, A. Bhowmik, M. Gill, R. Simpson (Royal Preston Hospital); A. Schofield, K. McArdle, M. Parmar (Royal Shrewsbury Hospital); M. Williamson, H. Burton, E. Courtney, C. Grant, A. Saracino (Royal United Hospital Bath); K. Newton, J. Epstein (Salford Royal NHS Foundation Trust); G. Branagan, M. Bignell, M. Symanekewicz (Salisbury District Hospital); S. Zaman, R. Mankotia, Z. Siddiqui, A. Torrance (Sandwell General Hospital); D. Artioukh, M. Eggleston, K. Gokul, D. Selwyn (Southport and Ormskirk Hospitals); J. Warusavitarne, P. Chandrasinghe, J. Grainger, C. A. Leo, C. J. Vaizey (St Mark's Hospital); G. Harris, B. Levy, A. Skull (St Richard's Hospital); M. Thaha, S. Ahmed, A. Garg, H. Patel, A. Ramsanahie (The Royal London Hospital, Barts Health NHS Trust); M. Mondragon-Pritchard, K. Cuinas Leon, G. Williams (The Royal Wolverhampton NHS Trust); A. Shukla, H. Brewer, J. Fitzgerald, H. Kho (United Lincolnshire Hospitals NHS Trust); J. Torkington, S. Tate, J. Wheat (University Hospital of Wales); S. Smolarek, E. Platt, B. Rossi, J. C. Tham (University Hospitals Plymouth NHS Trust); J. Knight, J. Richardson, A. Tzivanakis (University Hospital Southampton); M. Gregori, M. A. Ashraf, M. Atif, A. Birindelli, J. Santos (University Hospitals Birmingham NHS FT); N. Saffaf, M. I. Aslam, L. Canning (Warwick Hospital); N. Chandratreya, M. Bowen, B. Graham, Y. Hamad, M. Kaubrys (Weston General Hospital at Weston super Mare); Z. U. Chaudhry, C. Bhan, H. Mukhtar, A. Oshowo, J. Wilson (Whittington Hospital NHS Trust); J. Richardson, N. Gouvas, D. Nicol, S. Pandey, M. Zilvetti (Worcestershire Royal Hospital); A. Sharma, T. Fatayer, S. Mothe, M. Rahman (Wythenshawe Hospital, UHSM); N. Curtis, A. Allison, R. Dalton, N. Francis, J. Ockrim (Yeovil District Hospital).

Ukraine: G. Psaras, H. Dudarovaska, T. Marharint, E. Mostovoy, S. Voloshin (Mariupol Cancer Center); O. Kolesnik, D. Makhmudov (National Cancer Institute, Ukraine).

United States: Y. Altinel (Cleveland Clinic); A. Iqbal, L. Cunningham, K. Go, S. Tan (University of Florida).

~~ESCP Cohort Studies and Audits Committee~~

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~~Alaa El-Hussuna (2017 Audit Lead), Aneel Bhangu, Nicholas Buchs, Christianne Buskens, Sanjay Chaudri, Matteo Frasson, Gaetano Gallo, James Glasbey, Ana Minaya, Dion Morton, Ionut Negoï, Dmitri Nepogodiev, Francesco Pata, Luis Sánchez Guillén, Baljit Singh, Oded Zmora, Thomas Pinkney (Chair)~~

Statistical Analysis and Data Management

~~James Glasbey, Dmitri Nepogodiev, Rita Perry, Laura Magill, Aneel Bhangu (Guarantor)~~

ESCP Research Committee

~~Dion Morton (Chair), Willem Bemelman, Steven Brown, Christianne Buskens-Quentin Denost, Charles Knowles, Søren Laurberg, Jérémie Lefèvre, Gabriela Möeslein, Tom Pinkney, Carolynne Vaizey, Oded Zmora~~

Collaborators

~~Albania: S. Bilali, V. Bilali (University Hospital Center Mother Teresa);~~

~~Argentina: M. Salomon, M. Cillo, D. Estefania, J. Patron-Uriburu, H. Ruiz (Buenos Aires British Hospital); P. Farina, F. Carballo, S. Guckenheimer (Hospital Pirovano);~~

~~Australia: D. Proud, R. Brouwer, A. Bui, B. Nguyen, P. Smart (Austin Hospital); A. Warwick, J. Theodore (Redcliffe Hospital);~~

~~Austria: F. Herbst, T. Birsan, B. Dauser, S. Chaffari, N. Hartig (Barmherzige Brüeder, Wien); A. Stift, S. Argeny, L. Unger (Medical University of Vienna); R. Strouhal, A. Heuberger (Oberndorf b. Salzburg);~~

Belarus: A. Varabei, N. Lahodzich, A. Makhmudov, L. Selniachina (Minsk Regional Clinical Hospital).

Belgium: T. Feryn, T. Leupe, L. Maes, E. Reynvoet, K. Van Langenhove (AZ Sint-Jan Brugge); M. Nachtergaele (AZ St Jozef); B. Monami, D. Francart, C. Jehaes, S. Markiewicz, J. Weerts (Clinique St Joseph, Liege); K. Van Belle, B. Bomans, V. Cavenaile, Y. Nijs, M. Vertruyen (Europe Hospitals Brussels); P. Plotinckx, D. Claeys, B. Defoort, F. Muysoms, S. Van Cleven (Maria Middelares Gent); C. Lange, K. Vindevoghel (OLV van Lourdes Hospital Waregem); A. Wolthuis (University Hospital Leuven).

Bosnia and Herzegovina: M. Todorovic, S. Dabic, B. Kenjic, S. Lovric, J. Vidovic (JZU Hospital Sveti Vračevi); S. Delibegovic, Z. Mehmedovic (University Clinic Center Tuzla).

Brazil: A. Christiano, B. Lombardi, M. Marchiori Jr, V. Terciotti Jr (Hospital Centro Médico de Campinas).

Bulgaria: D. Dardanov, P. Petkov, L. Simonova, A. Yonkov, E. Zhivkov (Alexandrovska Hospital—First Surgery); S. Maslyankov, V. Pavlov, M. Sokolov, G. Todorov (Alexandrovska Hospital, Second Surgery Clinic); V. Stoyanov, I. Batashki, N. Iarumov, I. Lozev, B. Moshev (Medical Institute—Ministry of Interior); M. Slavchev, B. Atanasov, N. Belev, P. Krstev, R. Penkov (University Hospital—Eurohospital).

Croatia: G. Šantak, J. Čosić, A. Previšić, L. Vukušić, G. Zukanović (County Hospital Požega); M. Zelić, D. Kršul, V. Lekić Vitlov, D. Mendrila (University Hospital Rijeka).

Czech Republic: J. Orhalmi, T. Dusek, O. Maly, J. Paral, O. Setona (Charles University Hospital); M. Skrovina, V. Bencurik, M. Machackova (Complex Oncology Center Nový Jičín,

Surgical Department); Z. Kala, M. Farkašová, T. Grolich, V. Procházka (Surgical Department, University Hospital Brno); J. Hoch, P. Kocian, L. Martinek (University Hospital Motol, Prague); F. Antos, V. Pruchova (University Hospital Prague Bulovka).

Denmark: A. El Hussuna, A. Ceccotti, T. Madsbøll, D. Straarup, A. Uth Ovesen (Aalborg University Hospital); P. Christensen, P. Bondeven, P. Edling, H. Elfeki, V. Alexandrovich Gameza, S. Michelsen-Bach, I. Zheltiakova (Aarhus University Hospital/Randers Regional Hospital); PM. Krarup, A. Krogh, H. C. Rolff (Bispebjerg); J. Lykke, A. F. Juvik, H. H. K. Lóven, M. Marckman, J. T. F. Osterkamp (Herlev Hospital); A. H. Madsen, J. Worsøe (Hospital Unit West); A. Ugianskis (North Denmark Regional Hospital); M. D. Kjær, B. Youn-Cho-Lee (Odense University Hospital); A. Khalid, M. H. Kristensen (Regional Hospital Viborg).

Egypt: M. El Sorogy, A. Elgeidie, M. Elhemaly, A. ElNakeeb, M. Elrefai (Gastrointestinal Surgery Center, Mansoura University); M. Shalaby, S. Emile, W. Omar, A. Sakr, W. Thabet (Mansoura University Hospital); S. Awny, I. Metwally, B. Refky, N. Shams, M. Zuhdy (Oncology Center Mansoura University).

Finland: A. Lepistö, I. Keränen, A. Kivelä, T. Lehtonen, P. Siironen (Helsinki University Hospital); T. Rautio, M. Ahonen-Siirtola, K. Klintrup, K. Paarnio, H. Takala (Oulu University Hospital); M. Hyöty, E. Haukijärvi, S. M. Kotiluoto, K. Lehto, T. Tomminen (Tampere University Hospital); H. Huhtinen, A. Carpelan, J. Karvonen, A. Rantala, P. Varpe (Turku University Hospital).

France: E. Cotte, Y. Francois, O. Glehen, G. Passot (Centre Hospitalier Lyon Sud); A. d'Alessandro, E. Chouillard, J. C. Etienne, E. Ghilles, B. Vinson-Bonnet (CHIPS); A. Germain, A. Ayav, L. Bresler (CHU Nancy-Brabois); R. Chevalier, Q. Denost, R. Didailler, E. Rullier

(Hopital Haut Leveque); E. Tiret, N. Chafai, J. Lefevre, Y. Parc (Hôpital Saint Antoine); I. Siolezneff, D. Mege (Timone Hospital); Z. Lakkis (University Hospital of Besancon); M. Barussaud (University Hospital of Poitiers).

Germany: C. Krones, B. Bock, R. Webler (Marienhospital Aachen); J. Baral, T. Lang, S. Münch, F. Pullig, M. Schön (Städtisches Klinikum Karlsruhe); S. Hinz, T. Becker, T. Möller, F. Richter, C. Schafmayer (University Hospital Schleswig-Holstein, Kiel); J. Hardt, P. Kienle (University Medical Center Mannheim); F. Crescenti, M. Ahmad, Y. Soleiman (Verden KRH).

Greece: I. Papaconstantinou, A. Gklavas, K. Nastos, T. Theodosopoulos, A. Vezakis (Areteion Hospital); K. Stamou, A. Saridaki (Athens Bioclinic); E. Xynos, S. Paraskakis, N. Zervakis (Creta-InterClinic Hospital); G. Skroubis, T. Amanatidis, S. Germanos, I. Maroulis, G. Papadopoulos (General University Hospital of Patras); N. Dimitriou, A. Alexandrou, E. Felekouras, J. Griniatsos, I. Karavokyros (Laiko Hospital); A. Papadopoulos, G. Choularas, P. Ioannidis, D. Katsounis, E. Kefalou (Nikaia General Hospital); I. Katsoulis, D. Balalis, D. Manatakis (St. Savvas Cancer Hospital); G. Tzovaras, I. Baloyiannis, I. Mamaloudis (University Hospital of Larissa).

Hungary: G. Lázár, S. Ábraham, A. Paszt, Z. Simonka (Department of Surgery, University of Szeged); A. Zaránd, Z. Baranyai, G. Ferreira, L. Harsányi, P. Ónody (Semmelweis University, 1st Clinic of Surgery); B. Banky, Á. Burány, M. Lakatos, J. Marton, A. Solymosi (St. Borbála Hospital); I. Besznyák, A. Bursics, G. Papp, G. Saftics, I. Svastics (Uzsoki Hospital);

Iceland: E. Valsdottir, J. Atladottir, T. Jonsson, P. Moller, H. Sigurdsson (University Hospital of Iceland).

India: S. K. Gupta, S. Gupta, N. Kaul, S. Mohan, G. Sharma (Government Medical College, Jammu, Jammu and Kashmir, India); R. Wani, N. Chowdri, M. Khan, A. Mehraj, F. Parray (Sher-i-Kashmir Institute of Medical Sciences).

Ireland: A. Coveney, J. Burke, J. Deasy, S. El Masry, D. McNamara (Beaumont Hospital); M. F. Khan, R. Cahill, E. Faul, J. Mulsow, C. Shields (Mater Misericordiae University Hospital); M. E. Kelly, G. Bass, S. T. Martin, R. O'Connell, E. Ryan (St Vincent's Private Hospital); T. Connelly, G. Ahmad, W. Bukhari, F. Cooke (University Hospital Waterford).

Israel: O. Zmora, R. Gold Deutch, N. Haim, R. Lavy, A. Mosecovici (Assaf Harofe Medical Center); N. Shussman, R. Gefen, G. Marom, A. Pikarsky, D. Weiss (Hadassah Hebrew University Medical Center); S. Avital, N. Hermann, B. Raguán, M. Slavin, I. White (Meir Medical Center); N. Wasserberg, H. Arieli, N. Gurevich (RMC, Beilinson Campus); M. R. Freund, S. Dorot, G. Halfteck, P. Reissman, E. Yair (Shaare Zedek Mount Sinai); Y. Eden, R. Pery (Sheba Medical Center); H. Tulchinsky, A. Weizman (Sourasky Medical Center).

Italy: F. Agresta, R. Curinga, E. Finotti, G. Savino, L. A. Verza (Adria Hospital); C. R. Asteria, L. Boccia, A. Pascariello (ASST—Mantua); N. Tamini, A. Bugatti, L. Gianotti, M. Totis (Asst—Monza, Ospedale San Gerardo); L. Vincenti, V. Andriola, I. Giannini, E. Travaglio (Azienda Ospedaliero-Universitaria Consorziale Policlinico di Bari); R. Balestri, P. Buccianti, N. Roffi, E. Rossi, L. Urbani (Azienda Ospedaliero-Universitaria Pisana); A. Mellano, A. Cinquegrana (Candiolo Cancer Institute IRCCS); A. Lauretta, C. Belluco (Centro di Riferimento Oncologico, IRCCS, Aviano); M. Mistrangelo, M. E. Allaix, S. Arolfo, M. Morino, V. Testa (Citta della Salute e della Scienza di Torino); P. Delrio, U. Pace, D. Rega, D. Scala (Colorectal Surgical Oncology Istituto Nazionale per lo Studio e la Cura dei Tumori); G. Gallo, G. Clerico, S. Cornaglia, A. Realis-Luc, M. Trompetto (Department of Colorectal Surgery, S. Rita Clinic); G. Ugolini, N.

Antonacci, S. Fabbri, I. Montroni, D. Zattoni (Faenza Hospital); C. D'Urbano, A. Cornelli, M. Viti (G. Salvini); M. Inama, M. Bacchion, A. Casaril, H. Impellizzeri, G. Moretto (Hospital Dott. Pederzoli); A. Spinelli, M. Carvello, G. David, F. Di Candido, M. Sacchi (Humanitas Research Hospital); A. Frontali, V. Ceriani, M. Molteni (IRCCS MultiMedica); R. Rosati, F. Aleotti, U. Elmore, M. Lemma, A. Vignali (IRCCS Ospedale San Raffaele); S. Scabini, G. Casoni Pattacini, A. Luzzi, E. Romairone (IRCCS San Martino IST); F. Marino, D. Lorusso, F. Pezzolla (IRCCS 'Saverio de Bellis'); F. Colombo, C. Baldi, D. Foschi, G. Sampietro, L. Sorrentino (L. Sacco University Hospital); S. Di Saverio, A. Birindelli, E. Segalini, D. Spacca (Maggiore Hospital); G. M. Romano, A. Belli, F. Bianco, S. De franciscis, A. Falato (National Cancer Institute Naples); A. Muratore, P. Marsanic (Ospedale Agnelli Pinerolo); S. Grimaldi, N. Castaldo, M. G. Ciolli, P. Picarella, R. Porfidia (Ospedale Convenzionato Villa Dei Fiori); S. Di Saverio, A. Birindelli, G. Tugnoli (Ospedale Maggiore); A. Bondurri, D. Cavallo, A. Maffioli, A. Pertusati (Ospedale Sacco Italy); F. Pulighe, F. Balestra, C. De Nisco, M. Pedda (Ospedale San Francesco); E. Opocher, M. Longhi, N. M. Mariani, N. Maroni, A. Pisani Coretti (Ospedale San Paolo); R. Galleano, P. Aonzo, G. Curletti, L. Reggiani (Ospedale Santa Corona); M. Marconi, L. Del Prete, M. Oldani, R. Pappalardo, S. Zaccone I (Ospedale Santa Maria delle Stelle); M. Scatizzi, M. Baraghini, S. Cantafio, F. Feroci, I. Giani (Ospedale Santo Stefano, Prato); R. Tutino, G. Cocorullo, G. Gulotta, L. Licari, G. Salamone (Policlinico 'P. Giaccone'); P. Sileri, F. Saraceno (Policlinico Tor Vergata); F. La Torre, P. Chirletti, D. Coletta, G. De Toma, A. Mingoli (Policlinico Umberto I 'Sapienza University'); M. Papandrea, E. De Luca, R. Sacco, G. Sammarco, G. Vescio (Policlinico Universitario di Catanzaro); V. Tonini, S. Bianchini, M. Cervellera, S. Vaccari (Policlinico universitario Sant'Orsola Malpighi, Universita degli Studi di Bologna); N. Cracco, G. Barugola, E. Bertocchi, R. Rossini, G. Ruffo (Sacro Cuore Don Calabria Hospital); A. Sartori, N. Clemente, M. De Luca, A. De Luca, G. Scaffidi (San Valentino Hospital); L. Lorenzen, G. Balducci, T. Bocchetti, M. Ferri, P. Mercantini (Sant'Andrea Hospital); F. Pata, S. Bauce, A.

Benevento, C. Bottini, P. R. Crapa (Sant' Antonio Abate Hospital, Gallarate); M. Rubbini, G. Anania, P. Carcoforo, G. Cavallesco, C. Feo (University Hospital of Ferrara).

Japan: T. Yamamoto (Yokkaichi Hazu Medical Centre).

Latvia: A. Sivins, G. Ancans, S. Gerkis, R. Lunis, A. Pcolkins (Latvia Oncology Center).

Lithuania: D. Venskutonis, S. Bradulskis, E. Dainius, A. Subocius, J. Vencius (Department of General Surgery, LSMU, Kaunas Clinical Hospital); P. Zeromskas, V. Eismiontas, V. Nutautiene, D. Simeikas, A. Tamosiunas (Klaipeda University Hospital); S. Svagzdys, T. Latkauskas, P. Lizdenis, Z. Saladzinskis, A. Tamelis (Lithuanian University of Health Sciences Hospital Kauno Klinikos); A. Dulskas, J. Kuliavas, N. E. Samalavicius (National Cancer Institute, Lithuania); T. Poskus, V. Jotautas, S. Mikalauskas, E. Poskus, K. Strupas (Vilnius University).

Malaysia: A. Zakaria, N. N. Lah, M. Wong, Z. Zain, Z. Zakaria (Hospital Universiti Sains Malaysia); L. Mazlan, Z. A. Mohd Azman, I. Sagap (UKM Medical Centre).

Malta: J. Psaila, P. Andrejevic, C. Cini, S. Ellul, K. Pace (Mater Dei Hospital). Morocco: M. Ahallat, M. Hamid, A. Hrra, M. A. Majbar, M. Raiss (Ibn Sina University Hospital).

Netherlands: E. Westerduin, W. Bemelman, C. Buskens, P. Tanis (Academic Medical Centre); P.C. van der Sluis, P.H. Davids, A. Pronk, A.H.W. Schiphorst, N. Smakman (Diakonessenhuis); D. Zimmerman, T. Koeter, J. Stijns, Y T. van Loon (Elisabeth TweeSteden Hospital); M. Vermaas, E. de Graaf, P. Doornebosch, P. van Hagen, O. van Ruler (Ijsselland Ziekenhuis); B. Toorenvliet, J. Nonner, I. van den Berg, L. van Steensel, W. Vles (Ikazia); J. Melenhorst, R. Orsini, R. Visschers (Maastricht University Medical Centre); C. Hoff (Medical Center

Leeuwarden); R. Blom, H. Marsman (Onze Lieve Vrouwe Gasthuis); I. Mulder, H. Cense, S. de Castro, A. Demirkiran, M. Hunfeld (Rode Kruis Ziekenhuis Bevenwijk); A. van Geloven, J. de Groef, E. Hendriks, M. Leeuwenburg, N. van Oorschot (Tergooi); F. Wit, C. Rupert, P. Veldman (Tjongerschans ziekenhuis); M. Keijzers, J. Konsten (VieCuri Medisch Centrum voor Noord Limburg); F. Den Boer, M. Corver (Zaans Medical Center); E. J. Boerma, L. Koolen, M. Martens, K. Van Wijck (Zuyderland Medical Center).

Norway: D. Ignjatovic, R. Breuer, B. Gurpreet, T. Oresland, T. Tetens Moe (Akershus University Hospital); A. Nesbakken, I. Flateh Backe, T. A. Wik (Oslo University Hospital); K. Radiya, T. Dehli, P. Gjessing, S. Norderval, K. Woll (University Hospital of North Norway).

Pakistan: M. Anwer, M. S. Qureshi (JPMC WARD 2); A. U. Qureshi, M. Billah, M. Y. Jawad, A. Raza, N. Urooj (King Edward Medical University/Mayo Hospital, Lahore).

People's Republic of China: X. Wang, L. Li (West China Hospital). Poland: D. Jajtner, B. Gasinski, W. Kabiesz (Beskidian Oncology Center); P. Walega, M. Romaniszyn (Third Department of General Surgery, Jagiellonian University Medical College); M. Zawadzki, R. Czarnecki, Z. Obuszko, M. Rzaca, M. Sitarska (Wojewódzki Szpital Specjalistyczny).

Portugal: P. Silva, A. Duarte, D. Gonçalves, M. Morais (Centro Hospitalar de S. João); N. Rama, J. Nobre, I. Sales (Centro Hospitalar Leiria, EPE); J. Costa Pereira, S. Costa, C. Costa Pereira, C. Insua, I. Romero (Centro Hospitalar Tâmega e Sousa); N. Figueiredo, J. Cunha, H. Domingos, P. Vieira (Champalimaud Foundation); M. Cunha, M. Americano, E. Amorim, J. Rachadell (Cirurgia 2 - CHA - Unidade Portimão); J. Carvas, I. Armas, P. Fernandes, C. Pires, R. Reis (Hospital de Bragança); R. Martins, M. Dos Santos, P. Henriques (Hospital de Faro, Centro Hospitalar do Algarve); O. Oliveira, M. Duarte, L. Ferreira, J. Miranda, N. Vilela (Hospital

Distrital de Santarém, E.P.E.); J. Corte Real, S. Carlos, M. Frois Borges, P. Moniz Pereira, J. Simões (Hospital Garcia de Orta); P. Silva-vaz, V. Bettencourt, A. Gouveia, H. Perez, R. Rainho (Unidade Local de Saúde de Castelo Branco).

Romania: V. Bintintan, C. Ciuce, G. Dindelegan, R. Scurtu, R. Seicean (Clinica Chirurgie I); D. Cristian, T. Burcos, F. Grama, D. M. Mandi, G. Richiteanu (Coltea Clinical Hospital); A. Miron, V. Calu, O. Enciu, M. Nadragea, R. Parvuletu (Elias Emergency Hospital); S. S. Mogoanta, A. Crafcuic, S. Paitici (Emergency County Hospital of Craiova); I. Negoii, M. Beuran, C. Ciubotaru, A. Prodan, M. Vartic (Emergency Hospital of Bucharest); V. Tomulescu, C. Copaescu (Ponderas Academic Hospital).

Russia: D. Popov, A. Sednev, A. Klimenko, A. Semenov, S. Vasilyev (City Hospital 9); A. Pozdnyakov, D. Cherdancev, D. Mahotin, A. Nesytykh, V. Samsonyuk (Krasnoyarsk Regional Clinical Hospital); I. Pravosudov, D. Ivlev, A. Karachun, K. Lebedev, D. Samsonov (N.N. Petrov Research Institute of Oncology); R. Aiupov, D. Feoktistov, M. Garipov, S. Nail, N. Tarasov (National Republic Oncology Center); A. Yanishev, A. Abelevich, A. Kokobelyan, M. Lebedeva, R. Luzan (Nizhny Novgorod Regional Clinical Hospital); A. Rasulov, H. Dzhumabaev, Z. Mamedli (Russian Cancer Research Center); A. Bedzhanyan (Russian Reserch Center of Surgery named after B.V.Petrovsky); A. Khazov, M. Khanevich, G. Khrykov (Saint Petersburg Clinical Oncological Health Center); S. Katorkin, P. Andreev, A. Chernov, O. Davidova, A. Zhuravlev (Samara State Medical University); S. Achkasov, D. Shakhmatov, Y. Shelygin, O. Sushkov, A. Vardanyan (State Scientific Centre of Coloproctology); A. Ilkanich, N. Barbashinov, V. Darvin, S. Onishchenko, Y. Veronin (Surgut District Hospital).

Serbia: Z. Krivokapić, G. Barišić, I. Dimitrijević, V. Marković, A. Sekulić (Clinic for Digestive Surgery I Surgical Clinic, Clinical Ceter of Serbia); G. Stanojevic, B. Brankovic, M. Nestorovic, V. Pecic, D. Petrovic (Clinic for General Surgery, Clinical Center Nis); I. Kostic, A. Aleksic, D.

Dabic, B. Maric, V. Perunicic (General Hospital Cacak); Z. Radovanovic, M. Djuric, D. Lukic, D. Radovanovic (Oncology Institute of Vojvodina); V. Cuk, V. Cuk, J. Juloski, M. Kenic, I. Krdzic (Surgical Clinic KBC Zvezdara).

Singapore: J. C. Ngu, Y. Y. Ng, N. Teo (Changi General Hospital).

Slovak Republic: J. Korcek, A. Lazorisak, (Faculty Hospital Nitra).

Slovenia: M. Rems, Š. Ramovš Trampuš (General Hospital Jesenice); A. Tomazic, J. Grosek, J. Kosir, G. Noreic (University Medical Centre Ljubljana).

Spain: V. Vigorita, N. Caceres, E. Casal, A. Ruano, I. Trostchansky (Alvaro Cunqueiro Hospital); T. Golda, A. Galvez Saldaña, E. Kreisler Moreno, J. Lopez Dominguez, M. Vila Tura (Bellvitge University Hospital); F. Labarga, P. Galvez, V. Maderuelo, C. Suero (Complejo Asistencial Universitario de Palencia); J. Bargallo, L. Cayetano, S. Lamas, M. C. Silva (Conserci Sanitari de Terrassa Hospital de Terrassa); J. C. Bernal-Sprekelsen, R. Gómez, S. Jareño, A. Ríos, D. Vercher (Consortio Hospital General Universitario); J.M. García-González, J. Cervera-Aldama, J. Ramos Prada, M. Santamaría-Olabarrieta (Cruces University Hospital); N. Borda, J. M. Enriquez-Navascués, Y. Saralegui (Donostia University Hospital); A. Calero-Lillo, S. Aznar-Puig, M. A. López-Lara, S. Muñoz-Collado, J. Valverde-Sintas (Fundacio Hospital Esperit Sant); P. Menendez, C. Leon (Gutierrez Ortega Hospital); N. Truan, R. Baldonado, D. Martínez, J. Otero, L. Solar (Hospital Central de Asturias); V. Turrado Rodriguez, F. de Lacy Oliver, A. M. Lacy Fortuny, B. Martin Perez, A. M. Otero Piñeiro (Hospital Clinic Barcelona); J. Paredes, F. Fernandez, M. J. Ladra, A. Paulos, D. Prieto (Hospital Clinico Universitario de Santiago de Compostela); J. P. Beltrán de Heredia, F. Blanco Antona, B. de Andrés Asenjo, C. Ferreras García, A. Romero de Diego (Hospital Clínico Universitario de Valladolid); E. Cordoba Diaz de

Laspra, E. Echazarreta Gallego, M. Elia Guedea (Hospital Clínico Universitario de Zaragoza); D. Escola, S. Martínez (Hospital Comarcal Alt Penedes); V. Primo Romaguera, R. Parreño, L. Pastor, E. Rosell (Hospital de Dénia); R. Lozoya Trujillo, R. Alós Company, M. D. Ruiz Carmona, A. Solana Bueno (Hospital de Sagunto); S. Salvans Ruiz, S. Alonso Gonçalves, M. Jiménez Toscano, M. Pascual Damieta, M. Pera Roman (Hospital Del Mar); E. M. Pellicer-Franco, J. A. García-Marin, M. Mengual-Ballester, V. Soria-Aledo, G. Valero-Navarro (Hospital Morales Meseguer); M. Vicente-Ruiz, C. García-Zamora, A. González-Gil, M. J. Montoya-Tabares, M. Paredes-Quiles (Hospital Rafael Mendez); J. Die Trill, P. Abadia, I. Moreno, J. D. Pina, D. Ramos Rubio (Hospital Ramon y Cajal); J. Escartin, J. L. Blas, J. Fernando, R. Ferrer, J. García-Egea (Hospital Royo Villanova); I. Pros, W. Martínez, J. Rius, M. Socías (Hospital Sant Joan de Déu de Martorell); D. Sabia, J. Castellví Valls, V. González Santin, S. Mompert García, L. Viso Pons (Hospital Sant Joan Despí Moises Broggi); D. Julià, A. Codina-Cazador, R. Farrés, N. Gómez, P. Planellas (Hospital Universitari de Girona Doctor Josep Trueta); M. Cuadrado, I. Camps (Hospital Universitari Germans Trias i Pujol); M. Rufas, J. Escoll, A. Fermiñán, P. Muriel, E. Sierra (Hospital Universitario Arnau de Vilanova de Lerida); C. Alvarez-Laso, P. Lora, H. Padin (Hospital Universitario de Cabueñes); J. García-Septiem, C. Bustamante, V. Jimenez, J. Jimenez-Miramon, J. L. Ramos (Hospital Universitario de Getafe); A. B. Gallardo, P. Benito, L. Colao, P. Galindo, C. Garcia (Hospital Universitario de Torrejón de Ardoz); A. Forero-Torres, A. Alonso Poza, B. Dieguez Fernandez, C. Gilsanz Martin, M. Hernandez-Garcia (Hospital Universitario del Sureste); J. A. Rojo López, J. M. Gil López, M. González Zunzárren, J. Martínez Alegre, J. P. Zorrilla Matilla (Hospital Universitario Infanta Sofía); A. Navarro-Sánchez, F. J. Alcalá Serrano, J. López Fernández, D. Montesdeoca Cabrera (Hospital Universitario Insular de Gran Canaria); M. Alvarez-Gallego, J. Guevara, I. Pascual Miguelañez, I. Rubio-Perez (Hospital Universitario La Paz); M. Gomez Ruiz, J. Alonso Martín, C. Cagigas-Fernández, J. Castillo-Diego (Hospital Universitario Marques de Valdecilla); J. A. Pando, C. Maristany, A. Muñoz-Duyos, A. Rada-Palomino, H. Vargas-Pierola (Hospital

Universitario Mutua Terrassa); E. Peña Ros, J. A. Benavides Buleje, J. M. Muñoz Camarena, P. A. Parra Baños, M. Ramirez Faraco (Hospital Universitario Reina Sofía); J. J. Arenal, M. A. Citores, J. L. Marcos, J. Sánchez, C. Tinoco (Hospital Universitario Río Hortega); L. J. García Flórez, R. D. Arias Pacheco, G. Mínguez Ruiz, N. Rodríguez Corral, A. Rodríguez Infante (Hospital Universitario San Agustín); M. J. Carrillo-López, M. M. Carrasco Prats, A. Lage Laredo, Á. Martínez Manzano, P. Rodríguez García (Hospital Universitario Santa Lucía); J. J. Segura-Sampedro, N. Alonso-Hernández, M. Fernandez Isart, M. Gamundi Cuesta, A. Ochogavía Segui (Hospital Universitario Son Espases); N. Ibañez, J. Abrisqueta, J. Lujan (Hospital Universitario Virgen de la Arrixaca); R. Gómez Pérez, E. Corrales Valero, C. Monje Salazar, E. Sanchiz Cardenas, R. Soler Humanes (Hospital Universitario Virgen de la Victoria); R. M. Jimenez-Rodriguez, F. De la Portilla, J. M. Diaz Pavon, A. M. Garcia Cabrera, M. L. Reyes-Diaz (Hospital Universitario Virgen del Rocío); E. Espin, F. Marinello, M. Martí, J. L. Sanchez, F. Vallribera (Hospital Valle de Hebron); F. J. Orts Mico, M. Ortin Navarro, M. Perez Climent, C. Serra Diaz (Hospital Virgen de los Lirios); M. Millan, A. Caro, J. Escuder, B. Espina, F. Feliu (Joan XXIII University Hospital); A. Climent Aira, A. Estévez Diz, M. T. Moreno Asencio, A. Varela Mato, R. Vázquez Bouzán (POVISA Hospital); A. M. Minaya-Bravo, M.M. Díez-Alonso, R. Villeta-Plaza (Príncipe de Asturias Hospital); H. Guadalajara, D. Alías, D. García Olmo, C. Pastor, I. Valverde (Quironsalud Publicos); A. Sanchez Romero, A. Gardea, M. Gil Santos, T. Nimmersgern, P. Serrano Paz (Unidad de Coloproctología, Hospital Vinalopó-Torre Vieja); M. Romero Simó, T. Blasco Segura, I. Caravaca García, D. Costa Navarro, A. Zarco-Pleguezuelos (University General Hospital of Alicante); L. Sánchez-Guillén, B. Flor-Lorente, M. Frasson, Á. García Granero, E. García Granero (University Hospital La Fe Valencia); B. Arencibia, J. Alonso, G. Febles, E. M. Nogués, C. Roque (University Hospital of Gran Canaria Dr. Negrín).

Sweden: J. Segelman, J. Nygren (Ersta Hospital); G. Nestler (Falu lasarett); M. Abraham-Nordling, M. Egenvall (Karolinska University Hospital); P. Myrelid, B. Jung, P. Loftås (Linköping University Hospital); M. L. Lydrup, N. Azahr, P. Buchwald, P. Mangell, I. Syk (Skane University Hospital); M. Nikberg, J. Carlander, A. Chabok, K. Smedh, C. Tiselius (Västmanlands Hospital Västerås); S. Haapaniemi, A. Benckert (Vrinnevi Hospital Norrköping).

Switzerland: M. Adamina, C. Freil-Lanter, C. Gingert, P. Müller, J. Schäfli (Kantonsspital Winterthur); L. Regusci, M. Brenna, F. Fasolini (Regional Hospital Mendrisio); H. Misteli, P. Kirchhoff, D. Oertli (University Hospital Basel, Switzerland); D. Hahnloser, D. Clerc, M. Hübner (University Hospital of Lausanne, CHUV); F. Ris, N. C. Buchs, M. Chevallay, P. Morel, B. Schiltz (University Hospitals Geneva).

Taiwan: J. Y. Wang, W-C. Su, C-W. Huang, C-J. Ma, H-L. Tsai (Kaohsiung Medical University Hospital).

Turkey: G. S. Özbacı, B. B. Özkan, U. Karabacak (19 Mayıs University Faculty of Medicine); D. Bugra (American Hospital); F. Agalar, H. Baloglu, I. Basoglu (Anadolu Medical Center [in aff with Johns Hopkins Med]); N. Okkabaz, E. Binboga, A. Biricik, A. Celik, E. Yavuz (Bagecilar Training and Research Hospital); A. E. Canda, C. Agalar, M. Fuzun, S. Sokmen, C. Terzi (Dokuz Eylul University); A. Isik (Erzincan University, Mengucek Gazi Training and Research Hospital); B. Karip, A. C. Bilgili (Fatih Sultan Mehmet Training and Research Hospital); S. Leventoglu, B. Aytac, A. Yıldız, O. Yuksel (Gazi University Medical School); H. Sinan, O. Hancerliogullari, S. Kaymak, O. Kozak, M. T. Ozer (Gulhane Training and Research Hospital); I. S. Sarici, O. Akca, M. U. Kalayci, Y. Kara (Kanuni Sultan Süleyman Training and Research Hospital); D. Bugra, O. Agcaoglu, E. Balik, O. Bayram (Koc University School of Medicine); U. Sungurtekin, U. Ozgen (Pamukkale University School of Medicine); S. Demirbas (TOBB ETU University Hospital); E. Öztürk, O. Isik, T. Yilmazlar (Uludag University School of Medicine); E.

Colak, S. Karagul, V. Kinas (University of Health Sciences, Samsun Training and Research Hospital).

UK: N. Fearnhead, I. Lord, P. Stewart (Addenbrooke's [Cambridge University] Hospital); M. Zammit (Basildon Hospital); S. Arnold, N. Battersby, J. Broadhurst, A. Mehta, F. Seretis (Basingstoke and North Hampshire Hospital); J. Shabbir, C. Jones, J. Kynaston (Bristol Royal Infirmary); D. Vimalachandran, E. Blower, C. McFaul, D. McWhirter, J. Pilkington (Countess of Chester Hospital); T. Wilson, M. Chowdhary (Doncaster Royal Infirmary); B. Stubbs, M. Abdalkoddus, C. Lai, N. Thavanesan, C. Yao (Dorset County Hospital); T. Agarwal, S. Dindyal, R. M. C. Hill, S. Reade, A. Slessor (Ealing Hospital); H. Paterson, A. Balfour, M. Boland, A. Geraghty, J. O'Kelly (Edinburgh Western General Hospital); P. Patel, S. Tezas (Furness General Hospital); S. Yahia, V. Jadhav, K. Marimuthu, A. Narayanan, B. Piramanayagam (George Eliot Hospital); N. Bradley, F. Buchanan, K. Paul, J. Singh, K. Thomson (Glasgow Royal Infirmary); S. Korsgen, M. Bedford, K. Lee, K. Leong (Good Hope Hospital); D. McArthur, A. Bhangu, S. Malik, I. Mohamed (Heartlands Hospital); P. Cunha, A. Pilavas (Homerton University Hospital NHS Trust); A. Reddy, S. Ahmed, A. Ahmed, J. Voll (James Cook University Hospital); V. Velchuru, R. Lal, B. Mirshekar-Syahkal (James Paget Hospital); M. Kassai, M. Aleem, S. Keogh-Bootland (Jersey General Hospital); P. Sarmah, S. Brown, R. Keegan, A. Kelkar, P. Sen (Kettering General Hospital); M. Oliveira-Cunha, S. Chaudhri, R. Fares, B. Singh, W. M. Thomas (Leicester General Hospital); M. I. Aslam, K. Boyle, D. Hemingway, A. Miller, M. Norwood (Leicester Royal Infirmary); S. Gurjar, M. Al-Saeedi, L. Anandan, A. Sudlow, N. Zampitis (Luton & Dunstable Hospital); K. Malik, M. Bogdan, C. Smart (Macclesfield District General Hospital); M. R. Iqbal, S. Bailey, D. Lawes, G. Omar, R. Tamhane (Maidstone and Tunbridge Wells NHS Trust); M. Evans, S. Ather, J. Lim, H. Nageswaran, G. Taylor (Morriston Hospital); L. Hunt, J. Nicholls (Musgrove Park Hospital); I. Shaikh, F. Muscara, J. O'Brien, E. Photi, A. Stearns (Norfolk and Norwich University Hospital); D. Meylemans, C. Cunningham, R.

Hompes (Oxford University Hospitals); A. Tennakoon, N. Kumarasinghe, M. Rao, I. Upanishad (Pilgrim Hospital); S. Smolarek, E. Platt, B. Rossi, J. C. Tham (Plymouth Hospital NHS Trust); J. Khan, N. Ahmad, Z. Shweejawee, S. Stefan (Queen Alexandra Hospital); N. Smart, I. Daniels, T. Gregoir, L. Longstaff, F. McDermott (Royal Devon & Exeter Hospital); M. Varcada, I. Dami, T. Gala, E. Moggia, K. Ratnatunga (Royal Free Hospital NHS Trust Hampstead); R. Harries, J. Hayes, G. Williams (Royal Gwent Hospital); T. Raymond, C. Bronder, E. Davies, P. Hawkin, O. Ryska (Royal Lancaster Infirmary); K. Ayrat, A. Beveridge, A. Bhowmik, M. Gill, R. Simpson (Royal Preston Hospital); A. Schofield, K. McArdle, M. Parmar (Royal Shrewsbury Hospital); M. Williamson, H. Burton, E. Courtney, C. Grant, A. Saracino (Royal United Hospital Bath); K. Newton, J. Epstein (Salford Royal NHS Foundation Trust); G. Branagan, M. Bignell, M. Symankewicz (Salisbury District Hospital); S. Zaman, R. Mankotia, Z. Siddiqui, A. Torrance (Sandwell General Hospital); D. Artioukh, M. Eggleston, K. Gokul, D. Selwyn (Southport and Ormskirk Hospitals); J. Warusavitarne, P. Chandrasinghe, J. Grainger, C. A. Leo, C. J. Vaizey (St Mark's Hospital); G. Harris, B. Levy, A. Skull (St Richard's Hospital); M. Thaha, S. Ahmed, A. Garg, H. Patel, A. Ramsanahie (The Royal London Hospital, Barts Health NHS Trust); M. Mondragon-Pritchard, K. Cuinas Leon, G. Williams (The Royal Wolverhampton NHS Trust); A. Shukla, H. Brewer, J. Fitzgerald, H. Kho (United Lincolnshire Hospitals NHS Trust); J. Torkington, S. Tate, J. Wheat (University Hospital of Wales); J. Knight, J. Richardson, A. Tzivanakis (University Hospital Southampton); M. Gregori, M. A. Ashraf, M. Atif, A. Birindelli, J. Santos (University Hospitals Birmingham NHS FT); N. Saffaf, M. I. Aslam, L. Canning (Warwick Hospital); N. Chandratreya, M. Bowen, B. Graham, Y. Hamad, M. Kaubrys (Weston General Hospital at Weston super Mare); Z. U. Chaudhry, C. Bhan, H. Mukhtar, A. Oshowo, J. Wilson (Whittington Hospital NHS Trust); J. Richardson, N. Gouvas, D. Nicol, S. Pandey, M. Zilvetti (Worcestershire Royal Hospital); A. Sharma, T. Fatayer, S. Mothe, M. Rahman (Wythenshawe Hospital, UHSM); N. Curtis, A. Allison, R. Dalton, N. Francis, J. Ockrim (Yeovil District Hospital).

Ukraine: G. Psaras, H. Dudarovaska, T. Marharint, E. Mostovoy, S. Voloshin (Mariupol Cancer Center); O. Kolesnik, D. Makhmudov (National Cancer Institute, Ukraine).

United States: Y. Altinel (Cleveland Clinic); A. Iqbal, L. Cunningham, K. Go, S. Tan (University of Florida).